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PATENT
CKIM 3.0-001

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of :
KIM :
: Group Art Unit: 1644
Application No. 09/615,437 :
: Examiner: P. HUYNH
Filed: July 13, 2000 :
: Date: November 9, 2000
For: BEE VENOM TREATMENT :
WITHOUT THE STING :
X

Assistant Commissioner for Patents
Washington, D.C. 20231

DECLARATION OF CHRISTOPHER M. KIM, M.D.

Sir:

Christopher M. Kim, M.D., a United States citizen residing at 252 Broad Street, Red Bank, N.J. 07701 hereby declares as follows:

1. I am the inventor of Bee Venom Treatment Without The Sting that is the subject of U.S. Patent Application No. 09/615,437 filed July 13, 2000.

2. In the beginning of January, 1999, I conceived of the idea of using a local anesthetic in combination with bee venom as a means of reducing the pain associated with bee venom injections. Some time after conception in January of 1999, two or three of my patients, secretly and without their knowledge, were provided with such formulations including bee venom and lidocaine. Their first five treatment sessions were conducted without anesthetic. All subsequent treatments were with venom and lidocaine and patients were questioned each time regarding pain and discomfort associated with each administration. The formulations and their methods of administration are described in the above-captioned patent application. After each of the patients completed their course of treatment, spanning six to eight weeks, I reviewed the results and concluded that the use of

lidocaine was promising. However, upon reviewing the data I had collected and my patients' comments, I noted that patients exhibited discomfort and irritation which did not appear to be associated with the bee venom. That is, it was not the type of irritation or discomfort which were typically associated with the use of bee venom alone. Based on these additional reports of pain and discomfort, and the limited number of patients used, it was impossible to determine whether or not the coordinated use of bee venom and an intradermally injected local anesthetic would, on the whole, improve patients' comfort during treatment.

3. Further experimentation began in March of 1999 in which I took another small group of three to four patients and used a bee venom formulation containing a lower amount of lidocaine. The order of testing remained the same. Unlike the first test group in which each patient received approximately 2mg of lidocaine per injection, patients in this group received 1mg of lidocaine per injection. Again, the course of treatment was six to eight weeks and therefore, the results were not available for analysis until the end of April or early May, 1999.

Again, the patients were treated in secret and without their knowledge. This was done to obtain an unbiased evaluation of pain reduction associated with their treatment. It was discovered in May of 1999 that the reduction in the amount of lidocaine did produce an improvement in terms of both the typical pain associated with venom treatments and the irritation which was not otherwise associated with the bee venom. Interestingly, despite the dramatic reduction in the amount of lidocaine introduced, benefits of using lidocaine in terms of reducing the irritation associated with bee venom injections were still apparent. While it was surprising that lidocaine worked at all, my observation was particularly surprising as the amount of lidocaine involved was now at the lower end of the range conventionally used for topical problems. This generally low

amount would usually be employed only when relatively less painful procedures were contemplated. When very painful procedures are used, lidocaine in amounts of 2% or even higher are often needed. Since bee venom can be extremely uncomfortable, it was expected that at least 2mg/injection would have been expected.

4. Further experimentation followed thereafter wherein it was determined that, most preferably, the amount of anesthetic to be administered could be as little as 0.1mg to about 0.3mg per injection to provide optimal results based on the injection of an equal amount of bee venom by weight. Despite the relatively little amount of local anesthetic used, a significant reduction in the pain associated with bee venom treatment was realized by the patients.

5. No disclosure of the formulations, the methods of their manufacture, the methods of their use, or the results obtained by their use was made prior to April 14, 1999.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issuing therefrom.

Date: 11/10/00

CHRISTOPHER M. KIM, M.D.

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